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THE VALUE OF MEDICAL TECHNOLOGY IN WOUND TREATMENT

Improving Quality of Life and Saving Costs

MEDICAL TECHNOLOGY
life changing
innovation

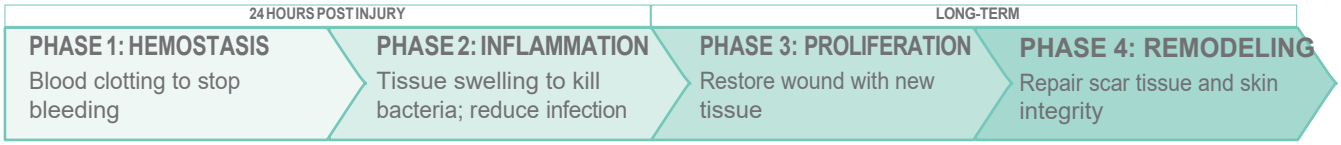
the disease

Chronic non-healing wounds are life-threatening, costly, and burdensome for the health system and the patients who have them. The ability to treat and address these wounds via the array of technologies that are available is imperative. Wound care is essential. Wounds are breaches in the structure of the skin that compromise skin function. They can be painful and lead to additional medical complications. Wounds become chronic when they have not completed the healing process (restoring tissue loss and skin function) in the expected time frame, usually within 30 days.[1] Typically, wounds are classified as chronic because they don't respond to initial treatment, or they persist despite appropriate care.[2]

- Chronic wounds typically occur on complex patients with multiple co-morbidities.
- The presence of an open, unhealed wound increases the patient's risk of infection and additional complications.
- Standard wound care may not be sufficient to jump start a stalled wound; advanced wound therapies can help reduce the total cost of care and help restore a patient's quality of life.

Health care costs continue to increase substantially, particularly for managing chronic wounds which is estimated to cost Medicare at least $28 billion annually.[3]

Four distinct phases exist in the healing process:[3]



Wounds may stall in the healing process due to many reasons, including restricted blood flow, poor nutrition, diabetes, immunosuppressive drugs, or poor mobility. Increases in scientific understanding of the cellular and biochemical steps involved in wound repair have spawned multiple new, advanced medical technologies that may be applied to manage non-healing wounds by addressing the underlying defect that has caused the wound to stall. Diabetic foot ulcers, venous leg ulcers, and pressure ulcers are the chronic wounds most often managed with advanced therapy intervention. Fife et al. compared real-world healing rates from the U.S. Wound Registry (USWR), a Qualified Clinical Data Registry with RCTs and publicly reported data and found that real-world data from the USWR and RCTs provide convincing evidence that the majority of patients (55–70%) do not achieve wound closure, in contrast to a mean publicly reported healing rate of 92%.[4]

DIABETIC FOOT ULCERS

Diabetic foot ulcers (DFUs) are one of the most common complications of diabetes. Patients with diabetes have a 15 percent risk over the course of their lives for developing a diabetic foot ulcer. Foot ulceration is the precursor to approximately 85 percent of lower extremity amputations in persons with diabetes.[5] Within five years, 45 to 55 percent of patients with neuropathic (complex, chronic pain) and ischemic (restriction in blood supply to tissues) DFUs, respectively, will die.[6]

VENOUS LEG ULCERS

An estimated two and a half million Americans are affected by venous leg ulcers (VLUs) each year at a cost of $14.9 billion to the health care system.[7] 13 to 29 percent of venous leg ulcers take more than two years to reach complete healing,[8] and of those, healed ulcers return at a rate as high as 60 to 70 percent.[9]

PRESSURE ULCERS

There are more than three million patients diagnosed with pressure ulcers (formerly known as bedsores, pressure sores, or decubitus ulcers) in the United States each year. The estimated cost of managing a single full-thickness pressure ulcer is nearly $70,000.[10] Vulnerable patients include the elderly, stroke victims, diabetics, dementia patients, patients in wheelchairs, and those who are bedridden or suffering from impaired mobility or sensation. U.S. expenditures for treating pressure ulcers have been estimated at $11 billion per year.[11]

SURGICAL WOUND DEHISENCE (SWD)

Surgical wound dehiscence is the separation of the margins of a closed surgical incision that has been made in skin, with or without exposure or protrusion of underlying tissue, organs or implants.

Separation may occur at single or multiple regions, or involve the full length of the incision, and may affect some or all tissue layers.

A dehisced incision may, or may not, display clinical signs and symptoms of infection.

Similar to SSI most dehiscence occurs 4-14 days post-operatively, a time-period of 30 days has been included in the grading system.

There is a WUWHS SWD Grading System that was developed during a consensus meeting.[12]

A retrospective analysis of the Medicare 5% Limited Data Set for calendar year 2014 included beneficiaries who experienced episodes of care for one or more of the following: arterial ulcers, chronic ulcers, diabetic foot ulcers, diabetic infections, pressure ulcers, skin disorders, skin infections, surgical wounds, surgical infections, traumatic wounds, venous ulcers, or venous infections. The main outcomes were the prevalence of each wound type, Medicare expenditure for each wound type and aggregate, and expenditure by type of service. The results of the study showed nearly 15% of Medicare beneficiaries (8.2 million) had at least one type of wound or infection (not pneumonia). Surgical infections were the largest prevalence category (4.0%). [3]

the treatment: medical technology

"Medical technology has helped to evolve wound treatment dramatically over the past 15 years."

Wound healing is a complex process relying on advanced medical technology to enhance results and improve patient care. Medical technology has helped to evolve wound treatment dramatically over the past 15 years from simple dressings to sophisticated, evidence-based options that treat and promote wound healing.[13]

Today, several types of wound treatment exist that are tailored to the specific type of wound and the unique needs of the patient.

CELLULAR AND/OR TISSUE BASED PRODUCTS FOR WOUNDS

Cellular and/or Tissue-Based Products (CTPs) aid wound repair through different mechanisms depending on their composition, construction and source materials. These mechanisms of repair range from maintenance of a biochemically-balanced, moist wound environment to structural support for tissue regeneration, and/or the provision of beneficial cells, cytokines and growth factors to the wound bed to support the activation of new tissue growth or granulation, decrease wound contracture and scar, and to regenerate skin.[14-19]
Randomized control trials have demonstrated that select CTPs[14--19]:

- Promote rapid closure of non-healing chronic wounds,
- Promote a higher percentage of wounds closed than conventional therapy, and
- Reduce the incidence of osteomyelitis (bone infection) and frequency of amputation.

According to ASTM International's "Standard Guide for Classification of Cellular and/or Tissue-Based Products (CTPs) for Skin Wounds" published in 2016, CTPs were defined "primarily by their composition and comprised of cells and/or the extracellular components of tissue."[6] CTPs may contain cells (viable or nonviable), tissue, proteins, and other materials intended to speed healing including synthetic components. CTPs can be classified on four composition categories: biosynthetic, biosynthetic and animal based, non-living tissue based, and living cells biological. Nonliving tissue-based CTPs are either human or animal-sourced. Living cells biological CTPs are minimally processed, cultured, animal sourced. Living cells CTPs are of human source and can contain fibroblasts, mesenchymal stem cells, and epithelial cells or keratinocytes within a matrix.[6]

OFF-LOADING THERAPY

Many chronic wounds arise on the plantar aspect of the foot often due of underlying metabolic or vascular conditions and in the case of diabetic foot ulcers, increased pressure undetected by the individual due to neuropathy. For successful wound healing to occur, repetitive stresses on the skin and underlying tissues must be eliminated and plantar pressure must be decreased. Off-loading, defined as any measure to eliminate abnormal pressure points, has been linked to the

success of healing and prevention of recurrence of diabetic foot ulcers.[20] Such means can include bed rest, crutches, wheelchairs, roll-a-bout scooters, walkers, total contact casts (TCC), removable cast walkers, custom splints, Charcot restraint orthotic walkers (CROW), extra-depth shoes, half-shoes, surgical shoes, felted foam, and bulky bandages. The effectiveness of these devices varies significantly, but the most effective offloading is achieved when forces are spread over a wide area of contact while ensuring compliance.[21-23]

TCC has been referred to as the gold standard in diabetic foot ulcer off-loading due to its superior healing rates.[23, 24] Randomized clinical studies and retrospective cohort studies report that 72-100% of patients heal with a traditional TCC in patients with diabetic foot ulcers.[25] However, a retrospective analysis of the U.S. Wound Registry from January 2, 2007 to January 6, 2013, found that only 2.2% of the 221,192 plantar ulcers registered were offloaded. Of those patients who did receive offloading, only 16% received a TCC; 36.9% were simply placed on a surgical shoe.[26] Alternative options include prefabricated TCC kits that are lighter in weight and easy to apply while providing pressure relief with positive clinical outcomes. [27]

NEGATIVE PRESSURE WOUND THERAPY

Negative Pressure Wound Therapy (NPWT) is the application of negative pressure to create an environment that promotes wound healing at the cellular level by promoting granulation tissue formation, promoting perfusion, and removing exudate and infectious material.[28]

NPWT has been shown to:

- Reduce incidence of emergent care and hospitalizations for pressure ulcer patients,[29]
- Reduce secondary amputations for patients with DFUs,[30] and
- Reduce healing time for patients with chronic wounds.[31]

MOBILE HEALTH AND TELEHEALTH IN WOUND CARE

The emergence of mobile health and telehealth technologies has created new opportunities for the diagnosis, monitoring, and treatment of wounds. These technologies offer the option of staging and tracking the progression of wound healing in a variety of care settings.[32]

ANTIMICROBIAL DRESSINGS

Antimicrobial dressings are wound dressings that have an antimicrobial agent acting as a barrier to prevent or help manage infection. Topical antiseptics act on multiple sites within microbial cells and reduce the likelihood of bacteria developing resistance.[33] Dressings incorporating these antimicrobials can play an important role in wound healing by providing an antimicrobial barrier and killing micro-organisms contained in the wound fluid absorbed into the dressing.

Innovation of antimicrobial dressings continues at a rapid pace using advanced medical technology. For example, new dressing technologies that control wound biofilm are being introduced. Biofilm is a grouping of bacteria encapsulated in a protective coating that adheres to wound surfaces. Biofilm is resistant to antibiotics and antimicrobial agents and may delay wound healing. Dressing technologies that disrupt biofilm allow antiseptics to more effectively kill bacteria in the wound fluid.

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COLLAGEN DRESSINGS

Chronic wounds trapped in the inflammatory phase will not progress to healing without resolving the inflammation. During the inflammatory phase, a wound attempts to cleanse itself of all non-viable tissue and debris by utilizing digestive enzymes to breakdown non-viable tissue and exudate to wash away the debris. The major classes of enzymes responsible for digesting non-viable tissue are the matrix metalloproteases (MMPs), including several that digest collagen. MMPs also degrade growth factors (i.e., protein chains) that regulate cell populations and activity. Collagen dressings absorb exudates while also providing a sacrificial substrate, which can serve to divert the MMPs from digesting newly formed tissue, thereby tipping the balance towards wound healing.

Collagen fundamental to the process of wound healing and skin formation. Collagen is known to support the regulation of extracellular components, which can assist in wound healing. There are a number of advanced wound-care dressings available that incorporate collagen. Some are comprised of Type I collagen and may be combined with other ingredients such as alginates or oxidized regenerated cellulose (ORC). In select populations, use of collagen dressings rather than saline-soaked gauze has been shown to reduce frequency of nursing visits and optimize wound healing time, subsequently reducing health care costs.[34]

THERAPEUTIC SUPPORT SURFACES

Pressure injuries (formerly known as pressure ulcers, bedsores, pressure sores, or decubitus ulcers) are areas of localized damage to the skin and underlying tissue due to pressure, shear, or friction. Pressure-redistribution beds, mattresses, and seat cushions are widely used as prevention aids in both institutional and non-institutional settings. Pressure redistribution is achieved by either increasing the body surface area that comes in contact with the support surface through immersion and envelopment or sequentially altering the parts of the body that bear load through repositioning or the provision of alternating pressure mattresses.[35] Support surfaces range in their ability to provide immersion and envelopment beginning at a foam surface that may be relatively hard, and is covered with stiff material, to the maximum amount of immersion and envelopment provided by air fluidized therapy beds.[36]

Support surfaces also may provide microclimate management, or air flow to the skin are beneficial for patients possibly due to mitigating the rise in skin temperature or moisture.[35] Similar to the example above, there is a significant difference in the ability of a support surface to provide microclimate management. Foam surfaces do not provide any airflow, and in fact impede normal perspiration due to the blocking of air flow at the skin/surface interface; low air loss surfaces provide a middle range of MCM and the highest microclimate management is provided by air fluidized therapy.

Risk factors for pressure injury have been described by Coleman et al (2014) as either conditions that are mechanical boundary conditions, such as mechanical load, or patient susceptibility and tolerance issues, such as mechanical properties of the tissue, or physiologic patient issues that lower the damage threshold. Consequently, a specific surface may or not be adequate for an individual patient depending on their condition. Patients must be monitored during hospitalization as to their skin health. Increases in surface technology should be provided when patients show signs of deterioration on their existing surface, or if their pressure injuries are not healing on the current surface. Patients also can be stepped down to lower technology surfaces when they resolve high acute states, such as ICU patients who are weaned off a ventilator or have resolved immediate medical challenges. [35-39]

"Compression pumps also provide advanced technology for patients with insufficient emptying of venous blood flow in the lower extremities."

COMPRESSION THERAPY

Compression therapy is the recognized treatment of choice for venous leg ulcers and chronic venous insufficiency. Non-healing venous ulcers and "mixed" ulcers with venous disease components exhibit varying degrees of lymphedema, which may respond to compression therapy.

Compression therapy systems, including hosiery, tubular bandages, and bandage systems, which are comprised of two or more layers or components, provide graduated compression externally to the lower limb to improve venous return and reduce edema. Bandages are commonly used for the treatment of active venous leg ulcers.

Compression pumps also provide advanced technology for patients with insufficient emptying of venous blood flow in the lower extremities.

Many patients, including those with venous disease and lymphedema, utilize these devices effectively to reduce swelling and to improve comfort. In addition, improved blood flow aids in the prevention of venous leg ulcers.[40]

medtech as a solution

Advanced wound care treatments can reduce the risk of pressure sores, ulcers, and infection; provide improved outcomes for patients; decrease hospitalization times; enhance quality of life; and improve cost savings for the U.S. health care system.

CLINICAL BENEFIT

Wounds are a serious health concern, causing great levels of patient pain, distress, and anxiety. The medical technology used in wound treatment benefits patients on many levels including:

- Lowering incidence of re-admission, additional surgeries, and complications,[41]
- Reducing amputation rates,[42,43]
- Reducing healing times,[44] and
- Reducing incidence of surgical dehiscence and infection.[45]
- Improved Quality of Life. *When negative patient factors (e.g. pain, anxiety, QoI) are addressed + coping mechanisms are gained (improve wellbeing) the wound healing may be improved.* [46,47]

ECONOMIC BENEFIT

Estimates indicate that wounds account for nearly four percent of health care system costs, and that number is rising.[48] The annual cost of managing wounds has been crudely estimated at $25 billion in the USA (Ref: Human skin wounds: a major and snowballing threat to public health and the economy. [49] Furthermore, studies show that products used to treat wounds can produce measurable cost savings to the health care system, including:

- Reducing cost of care in acute and post-acute settings, [50, 51]
- Reducing the risk of hospitalization and emerged care episodes,[52]
- Reducing total nursing time and wound related costs,[53] and
- Reducing the risk of repeat skin graft and associated length of hospital stay. [54]

The term ‘opportunity cost’ refers to the potential for used resources to achieve more value elsewhere in the healthcare system. [55] High opportunity costs occur with the overuse of ineffective treatments (or those that make a very small clinical difference), leading to wasted patient benefit and reduced value in the healthcare system. Conversely, underuse of treatments known to be effective also leads to waste. Since, there are a lot of wound care products available in the market, it is therefore important to follow peer-reviewed evidence-based guidelines in choosing the appropriate wound product in order to get an economic benefit. Considering health economic (cost-effectiveness) studies in reimbursement and coverage decisions will always lead to lower costs. [56]

The cost for leg ulcers will also accelerate when wounds persist for many years. Reduced working time and dressing frequencies and thus cost savings can be achieved by early detection of changes in the wound that result in worsening conditions, and subsequently providing prompt treatment before the wound requires more extensive care. Extended wound monitoring such as through technology-based interventions and early intervention with advanced wound products can be a solution. [57]

the future

Moving forward, advanced medical technology will play an increasing role in developing enhanced treatment and healing options that will ultimately improve the treatment and health of patients with chronic and non-healing wounds. At the annual meeting of the American College of Wound Healing and Tissue Repair, Dr. Amelia Bartholomew of the University of Chicago discussed new data suggesting it may one day be possible for humans to regenerate tissue for healing.[58]

The cost and incidence of chronic wounds is increasing, due in part to an aging population, increased prevalence of diabetes, and rising obesity. Failure of a wound to heal can have a profound effect on a patient's quality of life. Advanced medical technology is a solution.

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